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EXAMINER	
CARTER, KENDRA D	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/626,069	CAWTHON, GARRET D.	
	Examiner	Art Unit	
	Kendra D. Carter	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 July 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *39-53,57,60,74-76 and 87-94* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *39-53,57,60,74-76 and 87-94* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The Examiner acknowledges the applicant's remarks and arguments of July 20, 2007 made to the office action filed April 18, 2007. Claims 39-53,57,60,74-76 and 87-94 are pending. No claims were amended.

The Applicant's arguments of the 35 U.S.C. 112, first paragraph rejection of claims 39-53, 57, 60, 74-76 and 87-94 were found persuasive, and thus withdrawn.

For the reasons in the previous office action and below, the Applicant's arguments of the 35 U.S.C. 102(b) of claims 39, 49, 57, 74, 76, and 88 as being anticipated by Heilig (US 3,079,299) were found not persuasive, thus the rejection is upheld.

For the reasons in the previous office action and below, the Applicant's arguments of the 35 U.S.C. 103(a) of claims 40-50, 52, 53, and 60 as being unpatentable over Heilig (US 3,079,299) as applied to claims 39, 49, 57, 74, 76, and 88 above, in view of Paul et al. (US 6,217,890 B1), and in further view of Clark et al. (US 6,103,245) were found not persuasive, thus the rejection is upheld.

For the reasons in the previous office action and below, the Applicant's arguments of the 35 U.S.C. 103(a) of claims 51 and 52 as being unpatentable over

Heilig (US 3,079,299) as applied to claims 39, 49, 57, 74, 76, and 88 above, in view of Steuart et al. (US 5,330,756) were found not persuasive, thus the rejection is upheld.

For the reasons in the previous office action and below, the Applicant's arguments of the 35 U.S.C. 103(a) of claims 74, 75, 87, 89, 93 and 94 as being unpatentable over Heilig (US 3,079,299) as applied to claims 39, 49, 57, 74, 76, and 88 above, in view of Ando (US 5,881,925) were found not persuasive, thus the rejection is upheld.

For the reasons in the previous office action and below, the Applicant's arguments of the 35 U.S.C. 103(a) of claims 90 and 91 as being unpatentable over Heilig (US 3,079,299) as applied to claims 39, 49, 57, 74, 76, and 88 above, in view of Davies et al. (US 5,169,037) were found not persuasive, thus the rejection is upheld.

For the reasons in the previous office action and below, the Applicant's arguments of the 35 U.S.C. 103(a) of claims 90 and 92 as being unpatentable over Heilig (US 3,079,299) as applied to claims 39, 49, 57, 74, 76, and 88 above, in view of Hanson et al. (US 5,249,747) were found not persuasive, thus the rejection is upheld.

Due to no new amendments to the claims and the Applicant's arguments were found not persuasive, the previously made rejection is repeated below for convenience. The Applicant's arguments are addressed below.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 39, 49, 57, 74, 76, and 88 are rejected under 35 U.S.C. 102(b) as being anticipated by Heilig (US 3,079,299).

Heilig teaches a self-propelling medicinal ointment composition and method of application comprising mineral oil, a polyethylene resin (i.e. solid particulate material) and a volatile propellant for dispensing and applying to the part of the body to be treated (see title and column 1, lines 11-16; addresses claim 39). The preferred mineral oil is petrolatum (see column 8, lines 43 and 44; addresses claim 49). The composition is adapted to be atomized from a fluid-tight container (see column 1, lines 30-34), in which the volatile propellant is a liquefied compressed gas provided in sufficient proportion in the ointment composition to atomize it through the valve of the container in which it is stored under pressure to produce a uniform porous coating of the polyethylene ointment base with medicament dispersed therein (see column 2, lines 41-47; addresses claims 39, 74 and 88). The primary medicament includes an antiseptic, bactericidal, or antibiotic (see column 2, lines 56-58; addresses claim 57) in an aqueous or alcoholic

solution with an emulsifying agent (see column 8, lines 5-9; addresses claims 39 and 57). In 20 cases of dermatitis, including diaper rash, the spray provided rapid relief (see column 5, lines 42-45; addresses claim 39). In regards to claim 76, the volatile compound evaporating after passage through the atomizing spray dispenser an inherent property of a "volatile" compound released under pressure.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

(1) Claims 40-53, and 60 rejected under 35 U.S.C. 103(a) as being unpatentable over Heilig (US 3,079,299) as applied to claims 39, 49, 57, 74, 76, and 88 above, in

view of Paul et al. (US 6,217,890 B1), and in further view of Clark et al. (US 6,103,245).

Heilig teachings are as applied to claims 39, 49, 57, 74, 76, and 88 above.

Heilig does not teach zinc oxide as the particulate or its average particle size (claims 40-43 and 60). Silicone oil, particularly cyclomethicone or dimethicone and derivatives thereof is not taught (claim 45). Talc, paraffin wax, microcrystalline wax, calamine, kaolin, cod liver oil, plant based oil, or bees wax is also not taught (claims 46-48 and 50-53).

Paul et al. teaches an absorbent article for absorbing body fluids and exudates, such as disposable diapers and adult incontinence garments (see column 1, lines 19-23), which includes a lotion formulation or treatment composition which provides a skin health benefit, and/or have a reduced viability of microorganisms (see column 2, lines 56-58). The lotion formulation includes an emollient, a wax, optionally a viscosity enhancer, and other ingredients (see column 13, lines 57-59 and 64). The emollients act as lubricants to reduce the abrasiveness of the topsheet to the skin and, upon transfer to the skin, help to maintain the soft, smooth and pliable appearance of the skin (see column 13, lines 66, 67 to column 14, lines 1 and 2). Suitable emollients include vegetable based oils, mineral oils, natural or synthetic oils, silicone oils, lanolin and lanolin derivatives, kaolin and kaolin derivatives and the like and mixture thereof (se

column 14, lines 3-5; address claims 39, 44, 48, 49, 57). The wax in the lotion formulations primarily functions as an immobilizing agent for the emollient and any active ingredient. In addition to immobilizing the emollient and reducing it's tendency to migrate, the wax in the lotion formulation provides a tackiness, which improves the transfer to the skin of the wearer. The presence of the wax also modifies the mode of transfer in that the lotion tends to fracture or flake off instead of actually rubbing off onto the skin of the wearer which can lead to improved transfer to the skin. The wax may further function as an emollient, occlusive agent, moisturizer, barrier enhancer and combinations thereof (see column 14, lines 31-43). Suitable waxes include beeswax, C30 alkyl dimethicone, jojoba oil, microcrystalline wax, paraffin and mixtures thereof (see column 14, lines 44, 47, 49, 52-54, and 59; addresses claims 45, 46, 52, 53 and 57). A viscosity enhancer increases the viscosity to help stabilize the formulation on the bodyfacing surface on the topsheet and reduce migration and improve transfer to the skin (see column 15, lines 6-9). A suitable viscosity enhancer is polyethylene, talc or mixtures thereof (see column 15, lines 18 and 20; addresses claim 48). Active ingredients such as diaper rash skin protectants, which protect the injured or exposed skin or mucous membrane surface from harmful or annoying stimuli are included (see column 15, lines 31-36). Suitable active ingredients include calamine, dimethicone, cod liver oil, kaolin and its derivatives, lanolin and its derivatives, mineral oil, talc, zinc oxide and mixture thereof from about 0.10 to about 95 weight percent (see column 15, lines 40-44; addresses claims 39, 40, 47-50, 53 and 57). To further enhance the benefit to the wearer, antimicrobial, antifungal, antiseptic, colarants, and fragrances can be added

(see column 15, lines 54, 55, 61, 62, and column 16 lines 6 and 7; addresses claim 57). The treatment composition is added to the topsheet by spraying (see column 23, lines 59 and 60).

Clark et al. teaches a composition for superior, longer-lasting barrier formulation as a protective barrier for incontinent patients along with managing diaper rash in humans (see column 4, lines 55-59). The inorganic barrier component zinc oxide is used and should be micronized to a particle size such that the barrier composition itself, after the addition of the inorganic component, is a smooth homogeneous composition that is essentially grit free (see column 7, lines 5-9 and claim 20). Zinc oxide has a mild astringent, protective and antiseptic action. Thus it is often used in the treatment of skin disorders and a number of epidermal infections (see column 7, lines 11-14).

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the method of Heilig and calamine, dimethicone, cod liver oil, kaolin and its derivatives, lanolin and its derivatives, mineral oil, talc, zinc oxide and mixture thereof because Paul et al. teaches the following: (1) the above ingredients are diaper rash skin protectants, which protect the injured or exposed skin or mucous membrane surface from harmful or annoying stimuli (see column 15, lines 31-36); (2) the composition may be sprayed (see column 23, lines 59 and 60). Therefore, using a known diaper rash skin protectant would be beneficial in a method to treat diaper rash.

Additionally, since the composition can be formulated into a spray, the above ingredients can be used in the method of Heilig.

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the method of Heilig and the average particle size of zinc oxide as disclosed in claims 40-43 and 60 because Clark et al. teaches that zinc oxide should be micronized to a particle size such that the barrier composition itself, after the addition of the inorganic component, is a smooth homogeneous composition that is essentially grit free (see column 7, lines 5-9 and claim 20). One skilled in the art would be able to determine the optimal particle size of zinc oxide by routine experimentation.

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the method of Heilig and beeswax, C30 alkyl dimethicone, jojoba oil, microcrystalline wax, paraffin and mixtures thereof (see column 14, lines 44, 47, 49, 53-54, and 59) is because Paul et al. teaches the following: (1) the above ingredients modify the mode of transfer in that the lotion tends to fracture or flake off instead of actually rubbing off onto the skin of the wearer which can lead to improved transfer to the skin. Additionally, the ingredients further function as an emollient, occlusive agent, moisturizer, barrier enhancer and combinations thereof (see column 14, lines 31-43); (2) the composition may be sprayed (see column 23, lines 59 and 60). Therefore, using ingredients that benefit the wearer of a diaper with the above

properties would be beneficial in a method to treat diaper rash. Additionally, since the composition can be formulated into a spray, the above ingredients can be used in the method of Heilig.

(2) Claims 51 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heilig (US 3,079,299) as applied to claims 39, 49, 57, 74, 76, and 88 above, in view of Steuart et al. (US 5,330,756).

Heilig teachings are as applied to claims 39, 49, 57, 74, 76, and 88 above.

Heilig does not teach calendula extract, chamomile extract, comfrey extract, or a plant based oil.

Steuart et al. teaches a method of treating a variety of skin conditions, such as diaper rash (see column 6, lines 19 and 20) with a therapeutic formulation comprising concentrated fluid plant extracts such as *S. officinale* (see abstract, lines 4, 5, and 11-14; column 4, line 45; and column 5, lines 29-32), and olive oil, castor oil, and jojoba oil (i.e. plant based oils; see column 10, example B2 and B3). Alcohol or glycol extract solutions of *S. officinale*, which is called "comfrey" has been recognized for decades for its healing properties, particularly for its ability to stimulate epithelial development externally in the case of skin damage (see column 1, lines 21, 21, and 61-64). The

formulations are formulated into a spray (see column 5, lines 50-53). In oil and water emulsion formulations, the oil is the dispersed phase for the purpose of protecting, moisturizing, and stimulating the healing processes of skin or mucous membrane (see column 5, lines 40-44).

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the method of Heilig and comfrey extract and a plant based oil because Steuart et al. teaches a method of treating diaper rash with and comfrey extract in a variety of plant based oils. The benefit of using comfrey extra in an oil is because of the following teachings by Steuart et al.: (1) comfrey extracts have been recognized for decades for its healing properties, particularly for its ability to stimulate epithelial development externally in the case of skin damage (see column 1, lines 21, 21, and 61-64); and (2) the oil is the dispersed phase for the purpose of protecting, moisturizing, and stimulating the healing processes of skin or mucous membrane (see column 5, lines 40-44). Additionally, since the composition can be formulated into a spray, the above ingredients can be used in the method of Heilig.

(3) Claims 74, 75, 87, 89, 93 and 94 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heilig (US 3,079,299) as applied to claims 39, 49, 57, 74, 76, and 88 above, in view of Ando (US 5,881,925).

Heilig teachings are as applied to claims 39, 49, 57, 74, 76, and 88 above.

Heilig does not teach a pump spray dispenser and a pressure release device (claims 74, 75 and 87). A piston-style dispenser, wherein pressure is maintained on the composition by pressure of the piston is also not taught (claim 89). Lastly, a manually actuated or reciprocating actuator spray delivery mechanism is not taught (claims 93 and 94).

Ando teaches a atomizer of the reciprocating pump type with a push button that is capable of being pressed with a finger, a piston which is pushed down by pressing the push button, a pressure chamber formed with the cylinder and the piston that has an inlet leading to the inside of the container and an outlet leading to the internal passage in the push button, the outlet of the pressure chamber moves against the force increased when the piston is pressed by the push button to open the above outlet (see column 1, lines 46 and 52-64; addresses claims 74, 75, 87, 89 and 94). Conventionally, atomizers that spray a mixture of liquid and powder are available such that the user shakes the mixture well in the container and then the push button is pressed. The atomizing tube is pushed in and opens the valve and the mixture is atomized through the nozzle (see column 1, lines 13, 14, and 18-23; addresses claim 93). The reciprocating pump type device provides an atomizer that is capable of stirring a mixture sufficiently and atomizing both powder and a liquid when used (see column 1, lines 24-32).

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the method of Heilig and a reciprocating pump type device with a piston-style dispenser, wherein pressure is maintained on the composition by pressure of the piston because Ando teaches the following: (1) reciprocating pump type with a push button that is capable of being pressed with a finger, a piston which is pushed down by pressing the push button, a pressure chamber formed with the cylinder and the piston that has an inlet leading to the inside of the container and an outlet leading to the internal passage in the push button, the outlet of the pressure chamber moves against the force increased when the piston is pressed by the push button to open the above outlet (see column 1, lines 46 and 52-64); and (2) the reciprocating pump type device provides an atomizer that is capable of stirring a mixture sufficiently and atomizing both powder and a liquid when used (see column 1, lines 24-32). Being that the applicant's method comprises a liquid and solid, this device would be suitable to deliver the diaper rash composition.

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the method of Heilig and a spray delivery comprising a manually actuated spray delivery mechanism is because as taught by Ando, it is the conventional way to atomize liquid and solid compositions (see column 1, lines 13, 14, and 18-23). Being that the applicant's method comprises a liquid and solid, this device would be suitable to deliver the diaper rash composition.

(4) Claims 90 and 91 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heilig (US 3,079,299) as applied to claims 39, 49, 57, 74, 76, and 88 above, in view of Davies et al. (US 5,169,037).

Heilig teachings are as applied to claims 39, 49, 57, 74, 76, and 88 above.

Heilig does not teach a bag-in-can-style dispenser, wherein the pressurized compartment is a polymeric bag received inside a rigid can or wherein the pressure is maintained upon the composition by a pressurizing gas received in the can and externally to the bag (claims 90 and 91).

Davies et al. teaches a product dispenser with a product bag. Pressure in the container surrounding the bag determines the dispensing pressure (see abstract, lines 1-4; addresses claims 90 and 91). The product bag is constructed of a suitable barrier material, which may take the form of a gas impervious material (see column 2, lines 6-8 and 31-33) and the height should be approximately equal to the different between the in inside can height (see column 7, line 51 and 52). The pressure regulating system is configured so as to permit product dispensing with an unrestricted orientation of the product dispenser while avoiding loss in product dispensing pressure or interruption of product dispensing (see column 2, lines 59-64). Additionally, the product has the following advantages: (1) the capability of choosing a starting pressure depending upon

the amount of product fill in the product bag together with a given can size and product bag size; and (2) off the shelf actuators which are cheaper and less prone to clogging than special units designed for wide range of pressure in the dispensing of the product can be used (see column 14, lines 36-45).

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the method of Heilig and a bag-in-can-style dispenser, wherein the pressurized compartment is a polymeric bag received inside a rigid can or wherein the pressure is maintained upon the composition by a pressurizing gas received in the can and externally to the bag because Davies et al. teaches the above bag-in-can style dispenser, which permits product dispensing with an unrestricted orientation of the product dispenser while avoiding loss in product dispensing pressure or interruption of product dispensing (see column 2, lines 59-64). Additionally, the product has the following advantages: (1) the capability of choosing a starting pressure depending upon the amount of product fill in the product bag together with a given can size and product bag size; and (2) off the shelf actuators which are cheaper and less prone to clogging than special units designed for wide range of pressure in the dispensing of the product can be used (see column 14, lines 36-45).

(5) Claims 90 and 92 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heilig (US 3,079,299) as applied to claims 39, 49, 57, 74, 76, and 88 above, in view of Hanson et al. (US 5,249,747).

Heilig teachings are as applied to claims 39, 49, 57, 74, 76, and 88 above.

Heilig does not teach a bag-in-can-style dispenser, wherein the pressurized compartment is a polymeric bag received inside a rigid can. Also, an elastic shape-memory bag wherein the pressure is maintained upon the composition by maintaining the bag in an expanded state is not taught.

Hanson et al. teaches a dispensing system for viscous fluids having a viscosity of greater than 60 cps (see column 3, lines 44-48), particularly vegetable oil containing compositions in closed pressurized containers such as bladder packs (see column 2, lines 8-13).

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the method of Heilig and the specific bag-in-can-style dispenser, bladder pack container (Applicant refers to an elastic shape-memory bag wherein the pressure is maintained upon the composition by maintaining the bag in an expanded state as a bladder pack container on page 25, paragraph 1, lines 6-8) because Hanson et al. teaches a dispensing system for viscous vegetable oil containing

compositions in closed pressurized containers such as bladder packs (see column 2, lines 8-13). Being that the applicant's method comprises a fluid base material with a viscosity from about 1 to 1000 cps (see specification page 12, paragraph 2, lines 1-4) that does not run off the skin (see claim 39) this device would be suitable to deliver the diaper rash composition.

Response to Arguments

Applicant's arguments filed July 20, 2007 have been fully considered but they are not persuasive.

35 U.S.C. 102(b) rejection

> The Applicant argues that the Heilig patent relates to an aerosol medicinal ointment composition (see column 2, lines 4-6). Because the Heilig patent, like the Adams reference, describes a composition delivered by an aerosol delivery mechanism, Applicant submits that it cannot and does not anticipate independent claim 39, which recites that "the dispenser is not an aerosol device."

The Examiner disagrees because although Heilig teaches a treatment for diaper rash primarily through an aerosol, Heilig teachings are taken as a whole. Heilig does not discourage use of the composition through other means. In particular, Helig teaches that "*The primary object of the invention is to provide a self-propelling fluid medicinal ointment composition adapted to be atomized from a fluid-tight container and*

which, when applied directly as a fine spray or mist to the part of the body to be treated..." (see column 1, lines 30-34.) Therefore, since there are other atomizing containers other then an aerosol known in the art, the composition is thus adapted to be dispensed from a variety of atomizers that does not have to include an aerosol device.

Claims 40-53, and 60 rejected under 35 U.S.C. 103(a) as being unpatentable over Heilig (US 3,079,299) as applied to claims 39, 49, 57, 74, 76, and 88 above, in view of Paul et al. (US 6,217,890 B1), and in further view of Clark et al. (US 6,103,245)

And

Claims 51 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heilig (US 3,079,299) as applied to claims 39, 49, 57, 74, 76, and 88 above, in view of Steuart et al. (US 5,330,756).

> The Applicant argues that the incorporation of ingredients from other references into the composition described in the Heilig patent would not alter that the Helig delivery system is an aerosol delivery system.

The Examiner disagrees for the reasons stated above in regards to Heilig teaching devices other than aerosol delivery systems.

Claims 74, 75, 87, 89, 93 and 94 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heilig (US 3,079,299) as applied to claims 39, 49, 57, 74, 76, and 88 above, in view of Ando (US 5,881,925);

Claims 90 and 91 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heilig (US 3,079,299) as applied to claims 39, 49, 57, 74, 76, and 88 above, in view of Davies et al. (US 5,169,037); and

Claims 90 and 92 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heilig (US 3,079,299) as applied to claims 39, 49, 57, 74, 76, and 88 above, in view of Hanson et al. (US 5,249,747).

> The Applicant argues that the Examiner's rationale for obviousness fails to establish a prima facie case of obviousness under Section 103(a) for several reasons, the most predominant of which is that these combinations would render the subject matter described in the Heilig patent unsuitable for its intended purpose. The delivery system described in the Geilig patent involves a highly viscous ointment that can only be delivered as described therein if it is first dispersed in a vary large amount of inert volatile propellant under high pressures to enable it to be delivered via an aerosol mechanism. Absent this aerosol mechanism, the ointment base described in the Heilig patent could not be sprayed, and would therefore be unsatisfactory for its intended use. Also, while aerosol delivery and non-aerosol delivery might be interchangeable mechanisms for delivery of compositions that are highly thinned, such a composition would run off of a surface on which it is sprayed, an therefore conflict with the subject matter recited in the pending claims. The cited references do not describe any compositions that meet the recited properties of sprayability and run-off resistance, that include solid particulate material and that are delivered using a non-aerosol stray delivery mechanism, as recited in the pending claims.

The Examiner disagrees because Heilig teaches that "*The primary object of the invention is to provide a self-propelling fluid medicinal ointment composition adapted to be atomized from a fluid-tight container and which, when applied directly as a fine spray or mist to the part of the body to be treated...*" (see column 1, lines 30-34.) There are other containers that atomize viscous compositions under pressure such as a bag-in-

can-style dispenser, bladder pack container as taught by Hanson et al. (see page 25, paragraph 1, lines 6-8). Thus, Heilig teaches a viscous composition that will not run-off of the treated area and can be used with other dispensing systems other that an aerosol device, which meets some of the limitations of the Applicant's claims. The other limitations have been addressed in the previous office action and above. In regards to the sprayability of the composition, the combined teachings of Heilig, Paul et al., Clark et al. and Steuart et al. teach all the components of the Applicant's method and composition. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case or either anticipation or obviousness has been established. Thus, the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

> The Applicant argues that the products encompassed by the pending claims won the top vote award at the MedAssets' New Technology Fair in October 2005, at which 47 preselected high-tech healthcare companies presented their new products. The panel of judges of the competition scored the product a 4.00 (based on a 4.00 scale) for being new and considered "breakthrough" technology, and an overall score of 3.90, which was #1 out of 47 companies. The Applicant has also been awarded a $50,000 grant as a winner of the 2006 Vogt Awards, recognizing the technical innovation of multiple embodiments of the pending claims. Applicant submits that this evidence also strongly supports the non-obviousness of the claimed subject matter.

The Examiner disagrees that the awards and scoring at a competition warrents evidence for supporting the non-obviousness of the claimed subject matter because the

above does not provide unexpected results compared to the closest prior art. It is noted that evidence of unexpected results must compare the claimed subject matter with the closest prior art to be effective to rebut a prima facie case of obviousness. In re Burckel, 592 F.2d 1175, 201 USPQ 67 (CCPA 1979).

> The Applicant notes that the Paul patent does not qualify as prior art because the application was filed August 23, 1999, which is after the effective filing date of the present application (July 30, 1999).

The Examiner disagrees because the Paul patent has a 102(e) date from the Provisional application No 60/141,788 filed on June 30, 1999.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kendra D. Carter whose telephone number is (571) 272-9034. The examiner can normally be reached on 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KDC

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER